Exergetic sustainability assessment of batch versus continuous manufacturing

Lessons learned in primary and secondary pharmaceutical manufacturing

Wouter De Soete

13.02.2014

Janssen Pharmaceutica NV
PDMS – Technical Operations - EHS²

Ghent University
Department of Sustainable Organic Chemistry and Technology

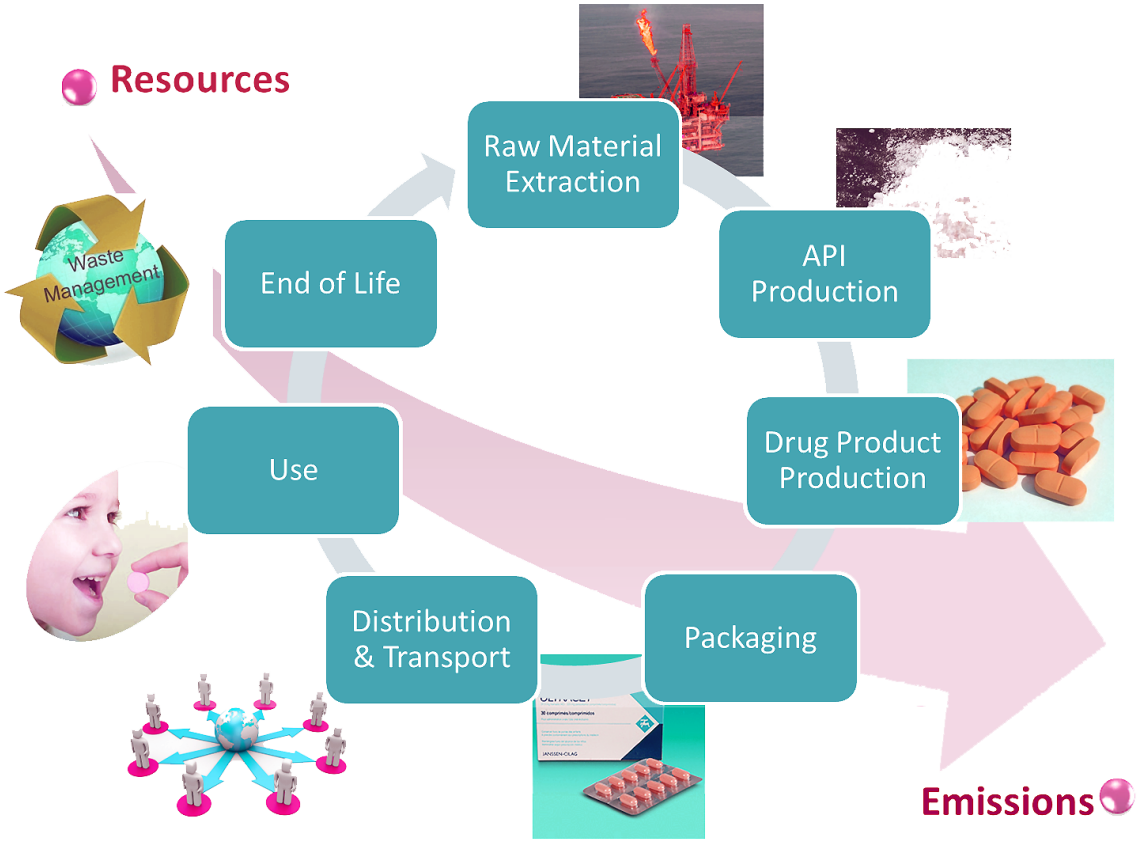
Introduction – Environmental Sustainability & Process Intensification (PI)

Introduction – Is PI Environmentally Sustainable?

PI: DO MORE WITH LESS

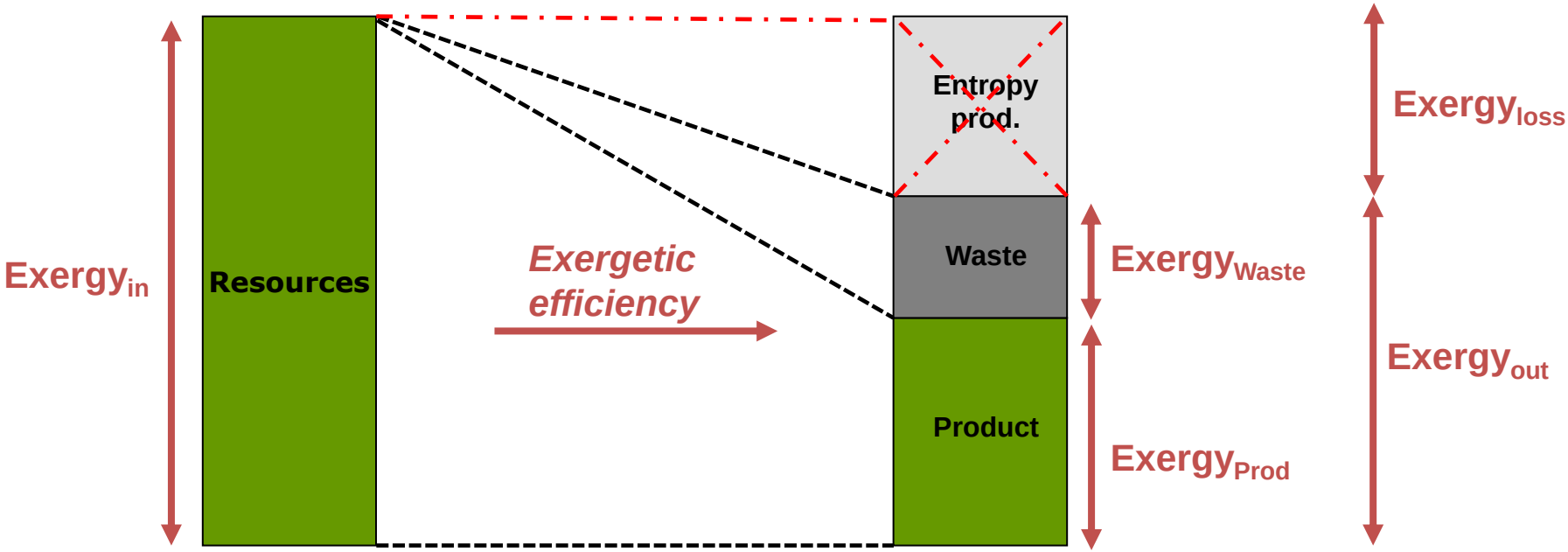
LESS/LEAN:
How to measure?

Take into account complete lifecycle of a product/service!



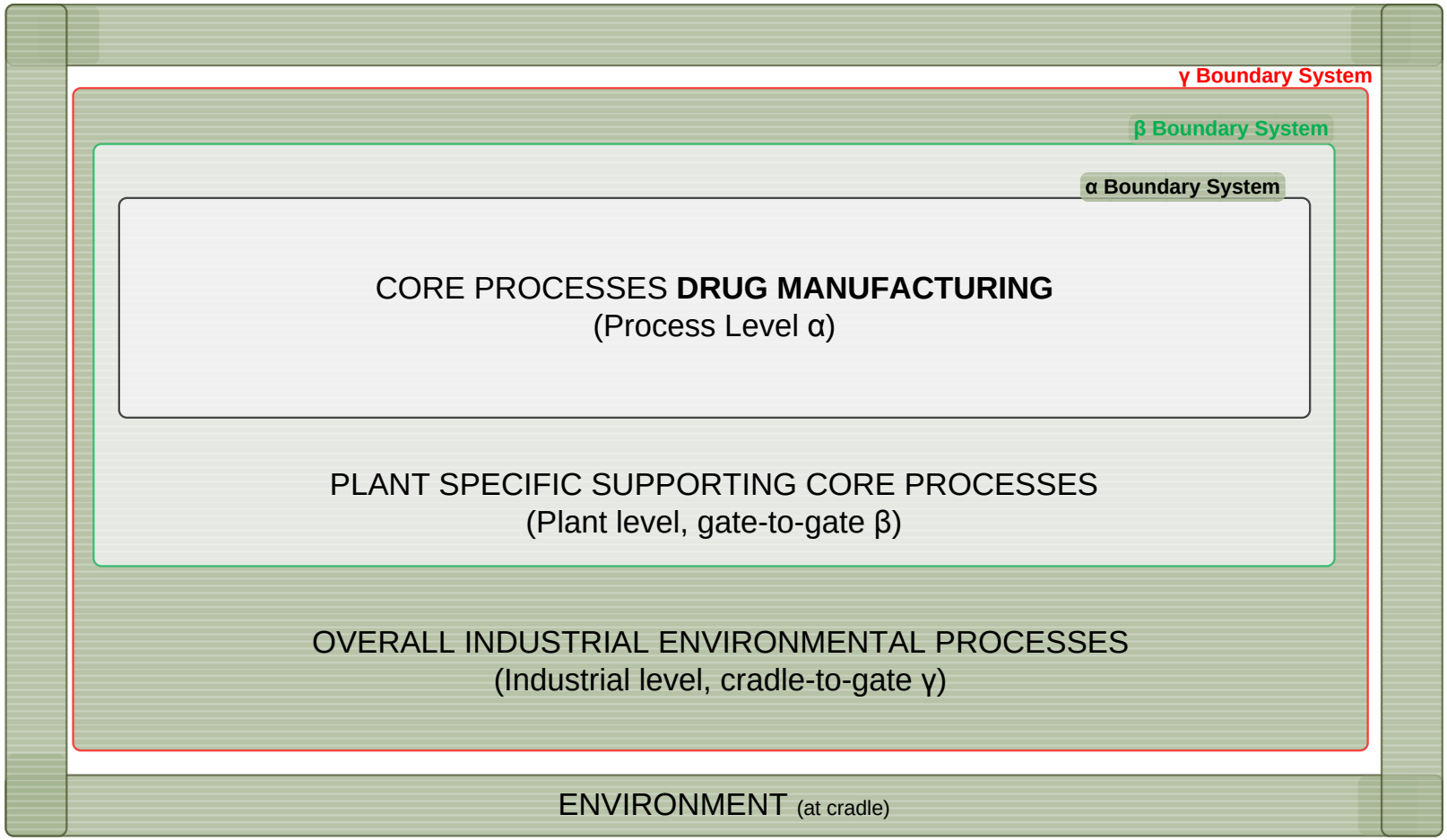
Introduction – How to measure?

- How to quantify all different kinds of resource? Energetic, physical resources?



Introduction – System boundaries

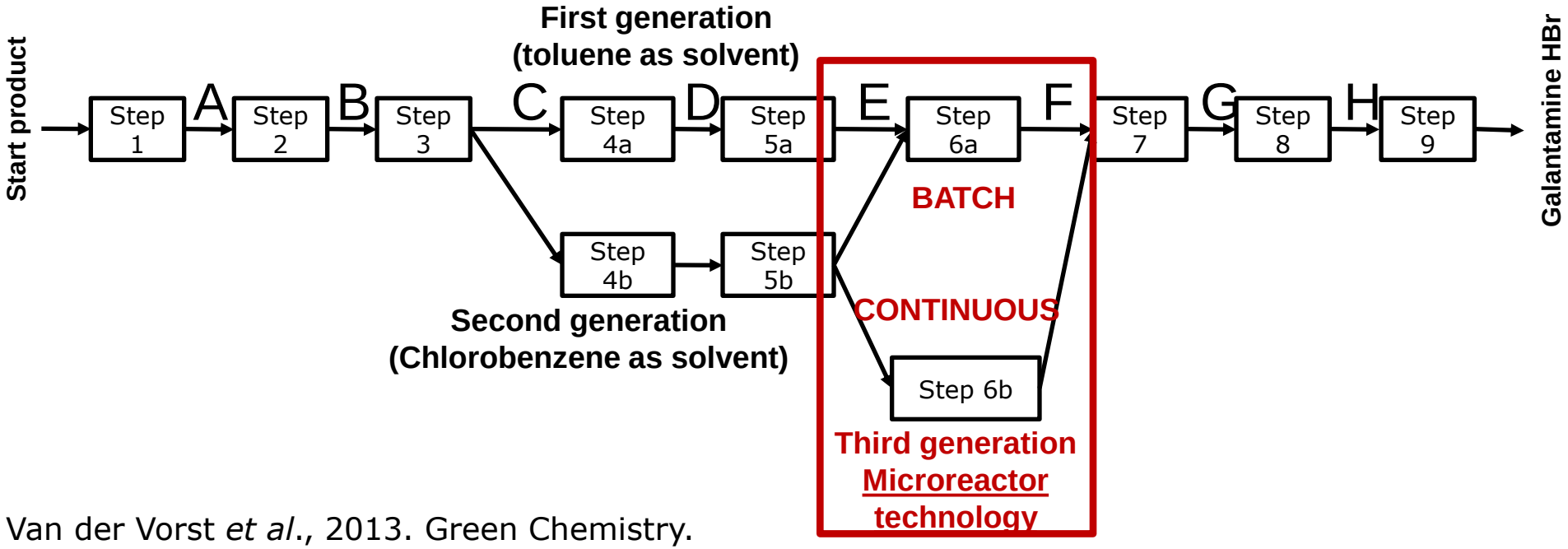
- Combination of Process Analysis (EA) and Life Cycle Analysis (ELCA)
  - Identification, localization and reduction of environmental burdens



Case 1: Primary Pharmaceutical Manufacturing (API)

Case 1: Three Galantamine generations

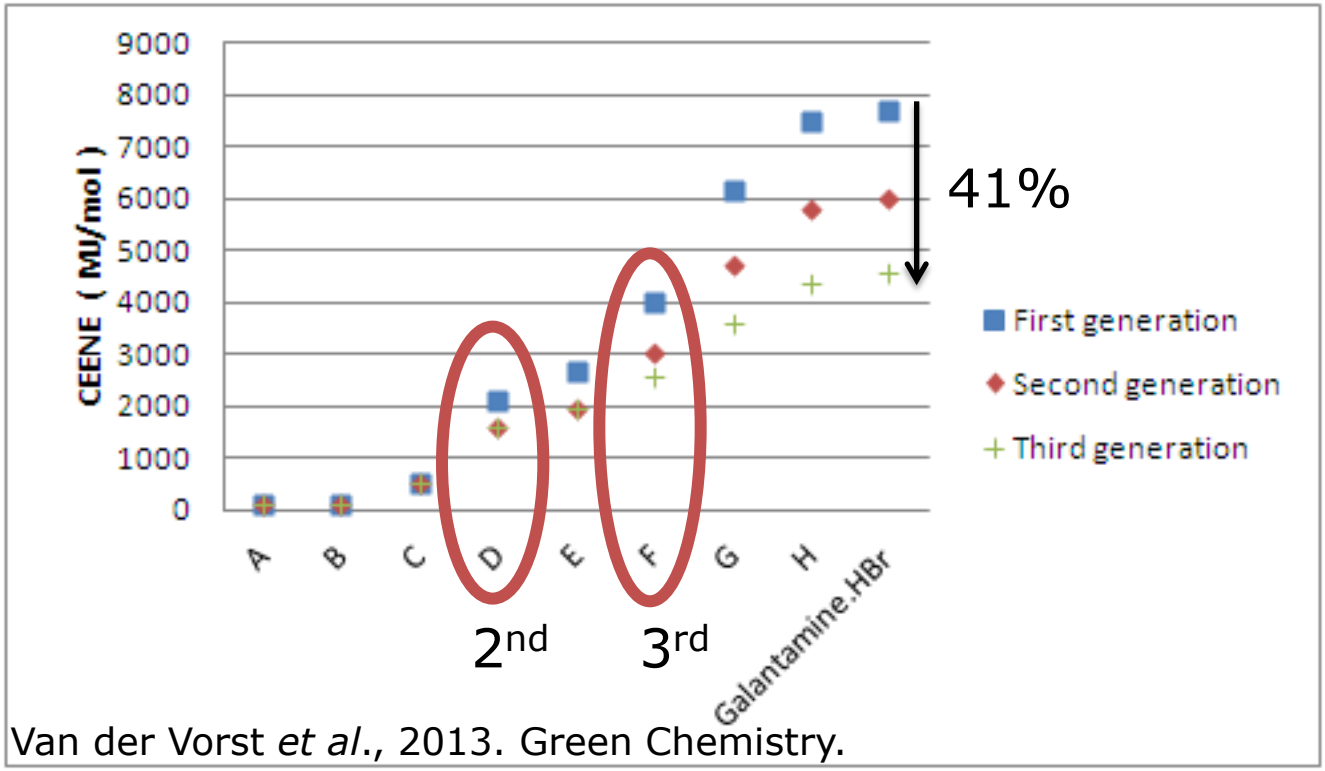
- Comparative environmental sustainability assessment of 3 generations of Galantamine
- Shift from **conventional batch** reactors to **continuous flow microreactors** in synthesis step 6



Van der Vorst *et al*., 2013. Green Chemistry.

Case 1: Three Galantamine generations

- +- 41% reduction in integral resource consumption of Galantamine synthesis steps (MJ_{ex}/mole intermediate)



Van der Vorst *et al*., 2013. Green Chemistry.

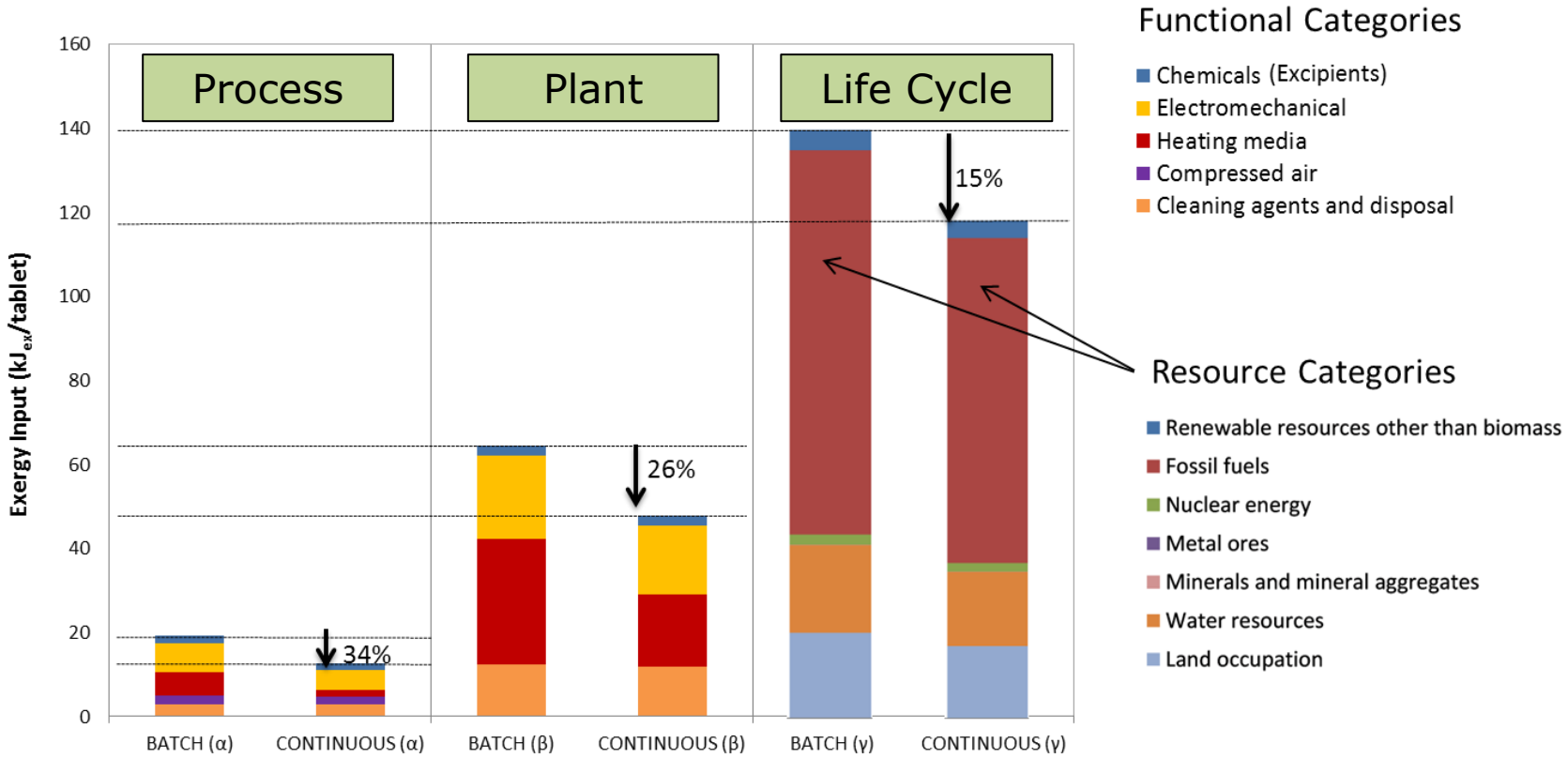
Case 2: Secondary Pharmaceutical Manufacturing (Dosage Forms)

Case 2: Tramacet Drug Product Production (tablet)

- Exergetic sustainability assessment of batch versus continuous wet granulation based pharmaceutical tablet manufacturing: a cohesive analysis at three different levels

De Soete *et al*., 2013. Green Chemistry.

Case 2: Tramacet Drug Product Production (tablet)

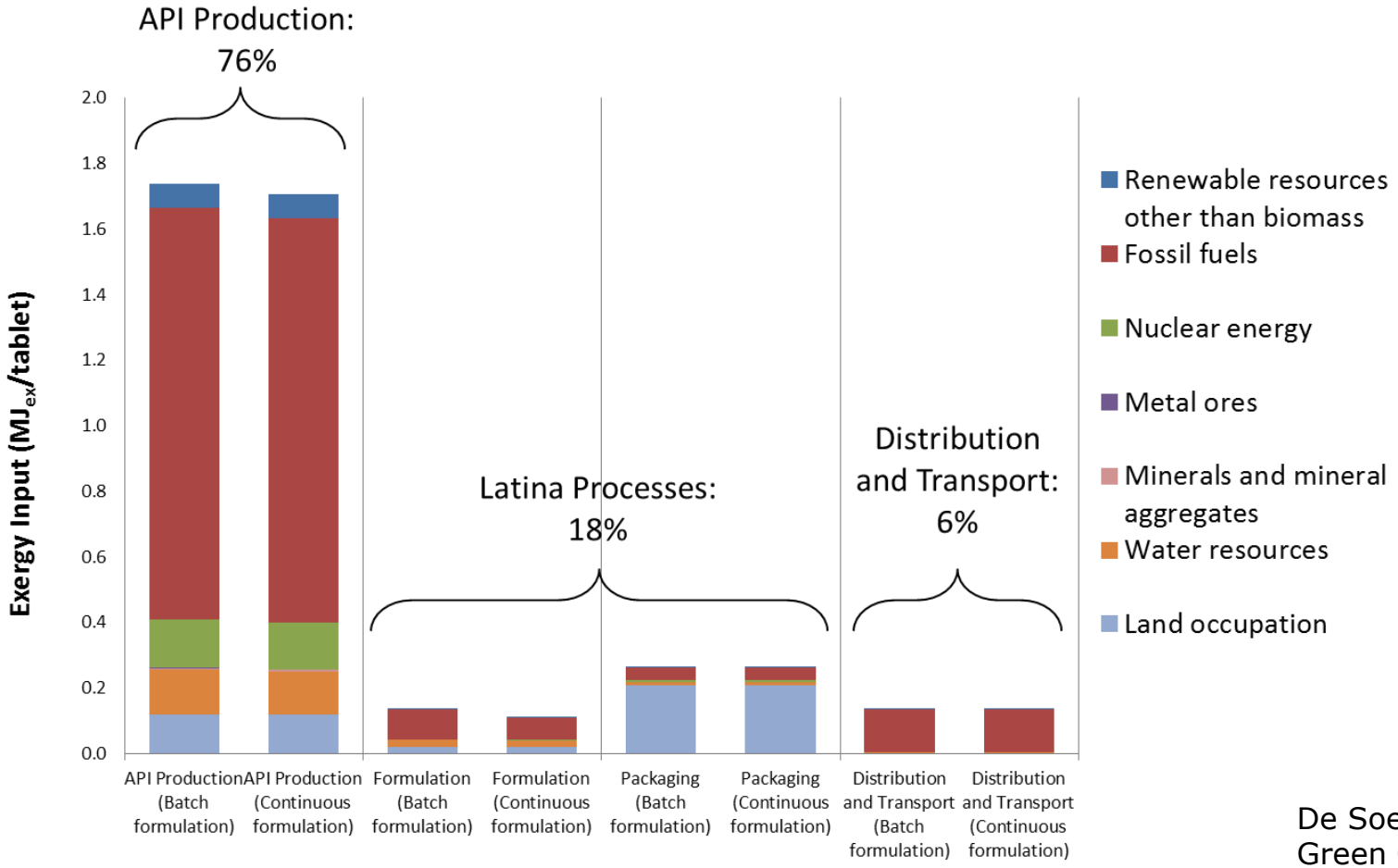


- **Tablet CEENE: 65% fossil, 15% water resources, 15% land occupation/biomass, 5% renewables resources other than biomass**

De Soete *et al.*, 2013. Green Chemistry.

Case 2: Tramacet - What about the supply chain?

- Prevailing for **high dose drugs** (TRAMACET® 82%$_w$ API)



De Soete *et al*., 2013. Green Chemistry.

Case 2: Tramacet – Final Results

- Huge step forward towards Greener Formulation Processes
- Further reduce impact through:
  - In-line blending and in-line coating
  - Re-using treated wastewater for cooling or cleaning purposes
  - Recycling exhaust air for heating purposes
- Sensitive parameters:
  - API dosage
  - # tablets per folding box (packaging)

De Soete *et al*., 2013. Green Chemistry.

Results overview and future outlook

- Substantial knowledge on environmental impact of API synthesis processes
- Need to move downstream in supply chain: what about distribution networks? Logistics? Use phase? Waste management?
- Need for generic forecasting models in R&D environments
- Take into account other impacts as well (e.g. Human Health)


Q&A

Thank You !

Contact: **Wouter.DeSoete@UGent.be**
wdesoete@its.jnj.com
+3292645948

Ghent University - Janssen Pharmaceutica
ENVOC - PDMS – Technical Operations - EHS²